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CONSENT QUALITY FOR GYNAECOLOGICAL SURGERY: HYSTERECTOMY AND THE MANAGEMENT OF THE ADNEXA FOR BENIGN DISEASE. A RETROSPECTIVE QUALITATIVE AUDIT

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ABSTRACT

Context: Patient involvement and shared decision making is essential when obtaining surgical consent. The circumstances in which surgical consent is given vary between and within organisations. The information provided to each patient should be consistent and evidence based. Risk management is impacted when there is conflicting data regarding surgical alternatives. In the field of gynaecology, this is particularly relevant to surgical consent for hysterectomy for benign reasons when considering additional options for prophylactic removal of fallopian tubes and/or ovaries.

Objective: To define the optimal consenting practice for benign hysterectomy with particular regards to management of the adnexa and compare current practice against this benchmark.

Design, Setting, Participants: Retrospective chart review study of a single tertiary teaching hospital in New Zealand. The included 116 participants underwent hysterectomy in 2014. Vaginal hysterectomy, acute surgery, suspected malignancy or previous bilateral salpino-oophorectomy (BSO) were excluded.

Interventions: Formulation and distribution of a standards statement to educate clinicians occurred in July 2014 with the aim of improving consent quality.

Main Outcome Measure: The individual components of high-quality consent were recorded giving a potential score of 0-6/6.

Results: 8% of the cohort overall received ideal consent. There was a trend to improvement following education on standards from 2% to 13%.

Conclusion: The majority of the women received inadequate information during the surgical consenting process for hysterectomy for benign disease.

KEY WORDS: Hysterectomy, Ovariectomy, Gynaecologic Surgical procedures, Salpingectomy, Ovary.

INTRODUCTION

Patient involvement and shared decision making is essential when obtaining surgical consent. The information provided to each patient should be consistent and evidence based, particularly where there is conflicting data. This is the situation with hysterectomy for benign reasons and specifically the prophylactic removal of fallopian tubes and to decrease the risk of ovarian cancer. To date there is a paucity of data that seeks to define or qualify the process and quality of consenting for benign gynaecological surgery.

Ovarian cancer is the second most common gynaecological malignancy and carries the highest case-to-fatality ratio[1]. There is a 1.4% prevalence by age 75 and 5-year survival of 43%[2]. There is no validated screening programme for its prevention and presentation is classically at an advanced stage[3].

Prophylactic BSO reduces ovarian cancer risk significantly[4]. A review of patients with ovarian malignancy showed that 20% had previous pelvic surgery and there would have been an estimated 30% reduction in malignancy had these patients undergone opportunistic BSO[5]. Jacoby et. al. in 2011 enrolled ~25,000 women and found no association between oophorectomy and cardiovascular disease (CVD), hip fracture, stroke or death[6].

Contrary to these findings the Nurses' Health Study in 2009 found a reduced risk of breast and ovarian cancer but an increase in mortality and CVD[7]. Parker et. al. confirmed that oophorectomy was associated with a decreased risk of ovarian cancer yet with numbers needed to treat of 220 and overall one additional mortality could be expected with every nine BSOs[8].

After a review of the relevant literature expected standards for surgical consent were formulated by consensus from the consultant gynaecologists in Wellington Regional Hospital. Local audit then tested the hypothesis that the quality of the consent received by patients undergoing hysterectomy differs from ideal standards in a significant proportion of cases. Our secondary objectives were to assess the impact of a consultant driven directive to define and improve consenting standards and to act as a pilot study for analysis of consent quality on a broader population.

MATERIALS AND METHODS

Study Design: Retrospective chart review study conducted from January 1st to December 31st 2014 in Wellington, New Zealand in a tertiary, teaching hospital. The researchers decided on a descriptive qualitative study design to inform local and international practice. The study, including design, was approved by the Capital and Coast District Health Board research committee. As this study conforms to the standards established by the NHMRC for ethical quality review, ethical approval was not required [9].

Study Population: We assessed the eligibility of all patients who underwent hysterectomy in 2014. The initial population was pooled from the operating theatre database, this was cross-referenced from the hardcopy diaries kept by theatre booking nurses. Cases were only stored by NHI (National Hospital Identifier) to maintain anonymity. The paper notes from clinics were requested and the NHIs were entered sequentially into Concerto®, Wellington Hospitals electronic record system. Hand written and dictated clinic notes, hand written and dictated operation notes and physical consent forms were all analysed. Age, menopausal status, proposed and actual procedure were recorded.

We excluded the following groups of patients; expected malignancy, vaginal hysterectomy, previous BSO, acute surgery, BRCA mutation, Lynch Syndrome or other high genetic risk for ovarian cancer.

Intervention: A meeting of all gynaecology consultants was arranged to define ideal consenting practice for hysterectomy specifically pertaining to the management of the adnexae. The standards statement that was generated by consensus opinion *(Appendix 1)* was circulated to all women's health staff involved in elective surgery in early June 2014 and presented at the Wellington Women's Health Forum. The intent of this intervention was to improve the quality of consent.

Study Outcomes: The following 6 categorical variables were recorded from the included cases;

- Provision of RANZCOG endorsed written information
- Plan for adnexal structures
- Risks of oophorectomy discussed
- Consented by consultant or trainee
- Consented in clinic, pre-assessment or on the day of surgery
- Consent countersigned by operating team on the day of surgery

Our primary outcome was to record the cases where ideal consent was performed. This was defined as a score of 6/6. Relative quality was also recorded. We defined adequate consent by a score of 4-5/6 and inadequate consent 0-3/6. The six factors comprising ideal consent were recorded individually to identify areas most in need of addressing.

As a secondary outcome the cases were divided into before and after the distribution of the standards statement for consent. A comparison of quality in these two groups was made.

Tertiary outcomes that also became evident as the data was collected were proportion of cases where the prosed and actual operation differed and the proportion of cases that were eligible for but did not receive prophylactic salpingectomy. An analysis of the time point when the operation plan changed and what the change entailed were included.

RESULTS

A total of 251 women were screened for eligibility criteria, 116 patients data were included in our final analysis. The age of patients ranged from 29 to 80, average 46 years, 11.2% were post-menopausal and only 2.5% over 65 years of age. Sixteen per cent of patients underwent BSO. Abdominal hysterectomy accounted for 66.4% of all operations with symptomatic fibroids and endometriosis the most common indications.

In assessing our primary outcome only 7.8% overall received ideal consent (6/6), 46.6% received adequate consent (4-5/6), 45.7% received inadequate consent (0-3/6). *(Figure 1)*

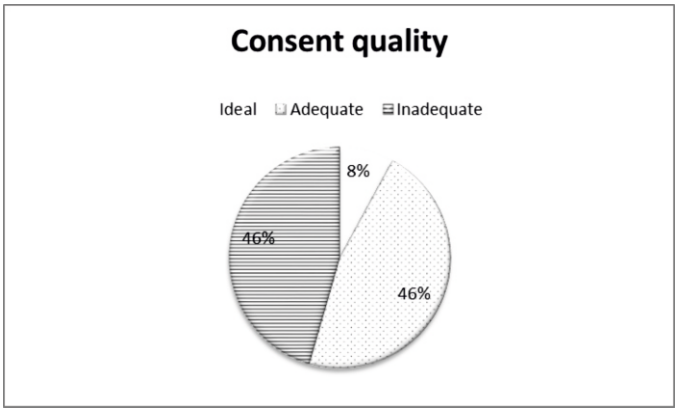

Figure 1 Consent Quality 2014

There was a non-significant trend to improvement following the distribution of the standards statement. Ideal consent improved from 1.9 to 12.5% (OR 7.29, 95% C.I. 0.88 – 60.29) and inadequate consent decreased from 53.8% to 39.1% (OR 0.55, 95% C.I. 0.26-1.15). *(Table 1, Figure 2)*

Table 1 Consent quality before and after distribution of standards statement

	Jan – June n=52		July – Dec n=64		Odds Ratio (95% C.I)†	P value
Ideal Consent	1	1.9%	8	12.5%	7.29 (0.88-60.29)	0.07 NS
Adequate Consent	23	44.2%	31	48.4%	1.18 (0.57-2.47)	0.65 NS
Inadequate Consent	28	53.8%	25	39.%	0.55 (0.26-1.15)	0.11 NS

† *95% Confidence Interval*

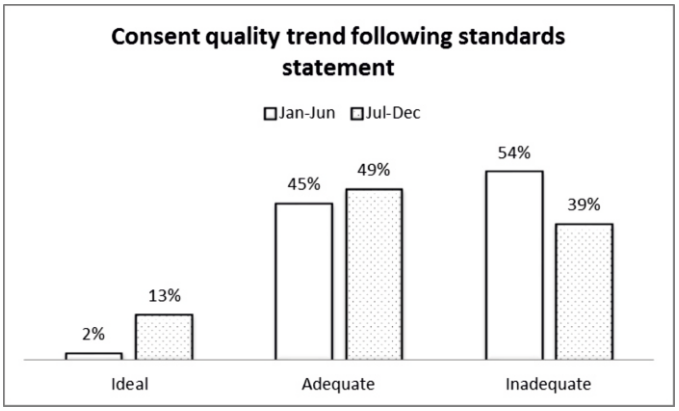

Figure 2 Consent quality before and after distribution of standards statement

The poorest areas of consent were the provision of the RANZCOG written information (29.3%) and discussing risks of Oophorectomy (37.1%). Conversely the majority (84.5%) were consented prior to the day of surgery. *(Figure 3)*

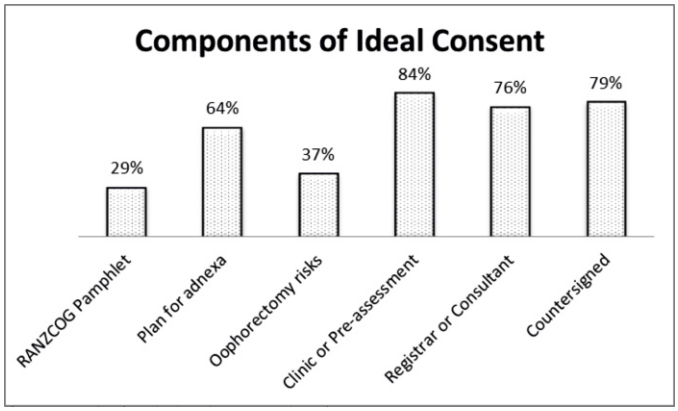

Figure 3 Contributing components of ideal consent

The principle domains of improved quality following the intervention were a discussion of the risks of oophorectomy and consent being given in either the outpatient clinic or pre-assessment clinic as opposed to on the day of surgery. Consent including the risks of oophorectomy improved from 2.9% to 45.3% (OR 2.25, 95% C.I 1.02 – 4.94). The percentage of patients consented in an optimal setting improved from 75.0% to 92.2% (OR 3.93, 95% C.I. 1.30 – 11.91). *(Table 2)*

Table 2 Consent quality before and after standards statement by contributing factor

	Jan – June n=52		Jul – Dec n=64		Odds Ratio (95% C.I)†	P value
RANZCOG pamphlet	14	26.9%	20	31.3%	1.23 (0.55-2.77)	0.61 NS
Plan for Adnexa	31	59.6%	43	67.2%	1.38 (0.65-2.97)	0.40 NS
Risks of Oophorectomy	14	26.9%	29	45.3%	2.25 (1.02-4.93)*	0.04*
Consent location	39	75.0%	59	92.2%	3.93 (1.30-11.91)*	0.02*
Consenting practitioner	41	78.8%	47	73.4%	0.74 (0.31-1.76)	0.50 NS
Countersigned	38	73.1%	54	84.4%	1.99 (0.80-4.95)	0.14 NS

† *95% Confidence Interval;* * *P < 0.05*

Fifty per cent of the population were eligible but were not consented for opportunistic salpingectomy *(Figure 4)*. There was a discrepancy in proposed and actual procedure in 54% of cases *(Figure 5)*. For 30 of 63 patients the discrepancy was an alteration in the type of hysterectomy, 29 of 63 alteration in salpingectomy and nine of 63 alteration in oophorectomy. Overall in 69.8% of these cases the discrepancy involved adnexal surgery. In only six of 63 cases the surgery was performed by a team that differed from the original consulting team. The procedure was predominantly changed intra-operatively; 41 of 63 cases, compared with five in pre-assessment and 17 pre-operatively.

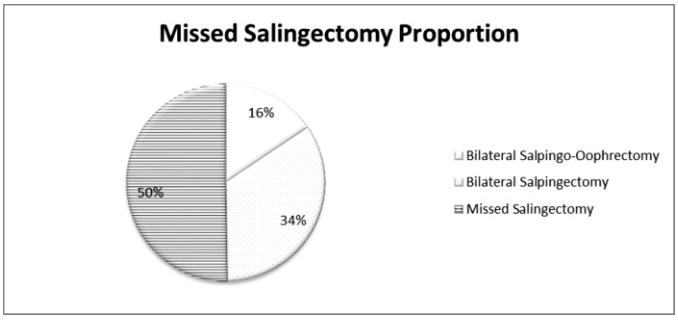

Figure 4 Proportion of cases with missed opportunistic salpingectomy

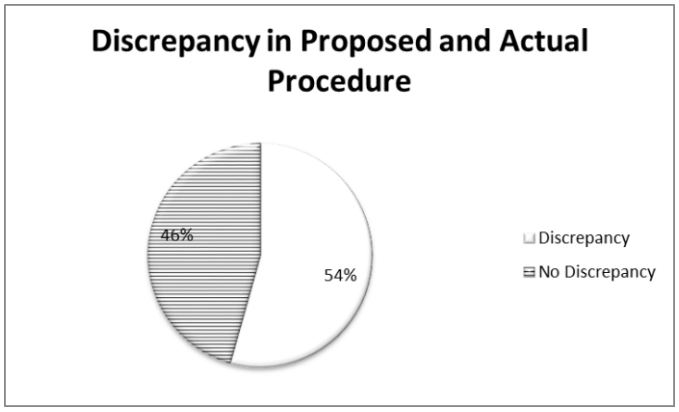

Figure 5 Proportion of cases with discrepancy between proposed/actual procedure

DISCUSSION

Ideal consent was obtained in eight per cent of cases, inadequate consent in 46%. For 54% of the patients the proposed surgery as initially planned differed from the actual surgery, 70% of which involved an alteration in the plan for adnexal surgery. The discrepancy arrived intra-operatively 65% of the time.

Informed consent as a primary endpoint is a difficult outcome for analysis and was not defined in the literature prior to the formation of local consensus opinion. This study was retrospective and not powered to assigned causality to our intervention. Regardless it is encouraging to see an, albeit not statistically significant, improvement in standards following a simple initiative. There is evidence for other interventions that could augment the observed improvement. Knowledge and recall is improved with written information further augmented by video[10,11,12]. This should be set at a low-literacy level[13]. A systematic review of randomised controlled trials from 2013 demonstrated significant improvement in satisfaction, decisional conflict and knowledge with decision aids, clinician training in shared decision making and institutional changes such as increased time allotted to consenting[14].

The population analysed had an average age of 46 years, 11% were post-menopausal and only 2.5% were over the age of 65. Sixteen per cent received BSO despite applying exclusion criteria designed to remove those at higher lifetime risk of developing ovarian cancer.

Oophorectomy significantly decreases ovarian cancer yet even the postmenopausal ovary continues producing oestradiol and testosterone which is thought to be protective against CVD, stroke, osteoporosis-related fracture, dementia and mood disorders[4,8]. Parker et. al. concluded that at no age oophorectomy increased survival and that benefit for ovarian conservation is evident until at least age 65 for patients undergoing hysterectomy for benign disease[7,15]. The Royal Australasian College of Obstetricians and Gynaecologists (RANZCOG) in 2014 advised women under the age of 65 require detailed discussion of the balance of risks with oophorectomy[16]. These results suggest further education of both clinicians and patients in this area would be beneficial.

An additional 58 patients (50%) could have received bilateral salpingectomy in the audit year yet this was not performed. Pathogenesis of high grade serous ovarian carcinoma is strongly linked to tubal intraepithelial lesions, no ovarian precursor lesions have been identified[17]. There is a reduced risk of clear cell and endometrioid ovarian carcinoma with salpingectomy and is thought not to significantly effect ovarian function [16,18].

Awareness of this topic is rising with the newest RANZCOG statement also encouraging opportunistic salpingectomy wherever possible[8]. There are international initiatives to increase uptake of salpingectomy at the time of hysterectomy for benign conditions, hence this is likely to rise locally as has been the case internationally[16,19]. The literature currently available on salpingectomy, however, is retrospective and prospective, long-term follow-up of patients that missed prophylactic salpingectomy would add to the evidence[18,19].

It is unlikely that improving quality of consent and patient care across most hospitals would be costly or time consuming. It would be interesting to include information from multiple centres and include other surgical procedures to further critically appraise practice. The authors plan on closing the audit loop on this topic with analysis of local data in 2017.

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Data Access and Responsibility: The principal investigator, Sam Lepine, had full access to all of the data in the study and takes responsibility for confidentiality and the integrity and accuracy of the results.

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APPENDICES

Appendix 1: Standards Statement distributed June 2nd 2014

Consent for surgery should be completed wherever possible in the outpatient clinic at the time of booking on the Waiting List by a consultant or sufficiently experienced registrar. There should be the provision of written information. There should be discussion and documentation of the risks associated with the procedure.

All aspects of the surgical plan that need to be deferred should be indicated on the booking form and the clinic letter. Any outstanding elements of the surgical plan that are to be agreed between the patient and surgeon on the day of surgery should be discussed in preadmission. Should the surgeon or patient be unhappy with any additional surgical procedures being performed prior to the proposed operation, surgery should be deferred with a repeat outpatient appointment made to clarify those issues.

All "+/-" abbreviations are to be replaced on consent form prior to entry into theatre with a clear surgical plan that has been formally agreed and finalised with written consent in preadmission. Hysterectomy +/- BSO is not acceptable. Consent for surgical procedures cannot be changed in the operating theatre.

All women consenting for hysterectomy must have explicit documentation regarding the surgical plan for ovaries. One of the following options is to be specifically written on the consent:

- Hysterectomy with ovarian conservation.
- Hysterectomy with bilateral salpingectomy and ovarian conservation.
- Hysterectomy with salpingo-oophrectomy – specifying unilateral or bilateral.
- Hysterectomy, with oophorectomy agreed if pathology is found intraoperatively.- specifying acceptance of risk of surgical menopause.